

OPTN/UNOS

Living Donor Committee

Three Proposals for Public Comment Regional Meetings - Fall 2011

Connie Davis, MD, Chair

Amy Waterman, PhD, vice Chair

Living Donor Committee

The Living Donor Committee develops policy and guidance related to the donation and transplantation of organs from living donors to recipients. The goal of the Committee's work is to continue to improve the informed choice of prospective living donors, and the safety, protection and follow-up of all living donors.

Significant Change in Living Donation Oversight

June 16, 2006 – Federal Register Notice- Secretary of HHS directed the OPTN to develop policies regarding living organ donors and organ donor recipients.

The notice stated:

- the consequence of centers non-compliance with living donor policy matches that of centers non-compliance with deceased donation policy; and
- policies should “promote the safety and efficacy of living donor transplantation for the donor and recipient.”

Change in Living Donation Oversight

Based on the Federal Register, the Living Donor Committee began this new area of work by proposing guidelines for the consent and medical evaluation of living kidney donors, which were sent for public comment in 2007.

Change in Living Donation Oversight

Public response was mixed.

Some respondents supported standardization of the consent and medical evaluation of living kidney donors.

Others opined that the proposed guidelines were:

- too prescriptive;
- dictated medical practice; and/or
- would lead to increased litigation.

Living Donation Oversight

The OPTN approved “voluntary guidance” for the consent and medical evaluation of living donors that have since been available through the OPTN website.

December 2009 - HRSA notified the OPTN that although helpful, the resources developed to date were not sufficient and that policies were still required.

Living Donation Policy Development

April 2010 - Representatives of the ASTS, the AST, NATCO, OPTN/UNOS, and HRSA met to discuss and develop a new process for incorporating clinical input into developing OPTN/UNOS policies with the potential to direct or prescribe medical care.

Living Donation Policy Development

The goal of the new process:

- earlier involvement from the professionals societies in any policy that might impact clinical practice;
- quicker policy development; and
- greater acceptance by the transplant community at large.

Living Donation Policy Development

A Joint Societies Policy Steering Committee (comprised of members from the AST, ASTS, NATCO, OPTN/UNOS, and HRSA) would be given an opportunity to make recommendations on any OPTN policy under development that has the potential to prescribe medical care, to include policies for the consent, medical evaluation, and follow-up of living donors.

Living Donation Policy Development

The Steering Committee formed a Joint Societies Work Group (JSWG) consisting of appointed members of the represented societies to develop recommendations for the consent, medical evaluation, and follow-up of living kidney donors.

Representatives of the Living Donor Committee participated on the workgroup in an advisory role, but did not vote on JSWG final recommendations.

Living Donation Policy Development

The JSWG created three resources representing the consensus of its members:

- Guidance document for Informed Consent of Living Kidney Donors;
- Position paper on the Medical and Psychosocial Evaluation of the Living Kidney Donor; and
- Recommendations for Donor Follow-up and Data Submission.

These resources are available for review as exhibits in the proposal(s)

Living Donation Policy Development

These JSWG resources were approved by the Executive Committees of the parent societies (AST, ASTS, and NATCO) and provided to UNOS and the Living Donor Committee for consideration in policy development.

Proposal to Establish Requirements for the Informed Consent of Living Kidney Donor

- Affected/Proposed Policies and Bylaws: 12.2 (Informed Consent of Living Donors); 12.4 (Independent Donor Advocates); UNOS Bylaws, Appendix B, Attachment I, Section XIII (Transplant Programs) D (2) Kidney Transplant Programs that Perform Living Donor Kidney Transplants

See the public comment document pages 96-105

Proposal to Establish Requirements for the Informed Consent of Living Kidney Donor

See the public comment document pages 96-105

This proposal includes eliminating related requirements from the OPTN/UNOS bylaws.

Specifically the requirement that kidney transplant programs that perform living donor kidney recovery must develop and once developed follow written protocols for the informed consent of living donors.

Proposal to Establish Requirements for the Informed Consent of Living Kidney Donor

Under this proposal existing bylaw requirements for Independent Donor Advocates (included in the JSWG position paper) have been copied verbatim and will be moved to an existing but currently empty Independent Donor Advocate policy (12.4) section.

Proposal to Establish Requirements for the Informed Consent of Living Kidney Donor

The current bylaws also contain a definition for the Independent Donor Advocate (not included in the JSWG position paper) which is proposed to move to policy (12.4) section as well.

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Proposal to Establish Requirements for the Medical Evaluation of Living Kidney Donor

- New Proposed Policy and Modification of the Bylaws: 12.3 (Medical Evaluation of Living Donors); UNOS Bylaws, Appendix B, Attachment I, Section XIII (Transplant Programs) D (2) Kidney Transplant Programs that Perform Living Donor Kidney Transplants.

See the public comment document pages 131-145

Proposal to Establish Requirements for the Medical Evaluation of Living Kidney Donor

See the public comment document pages 131-145

This proposal includes eliminating related requirements from the OPTN/UNOS bylaws.

Specifically the requirement that kidney transplant programs that perform living donor kidney recovery must develop and once developed follow written protocols for the medical evaluation of living donors.

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Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up

The Committee has reviewed available living donor data to establish performance metrics for transplant programs, but metrics have not been established because the data submitted on Living Donor Follow-up (LDF) forms remains too incomplete for analysis.

In response the Committee released a previous living donor follow-up policy proposal for public comment to require centers report a patient status for at least 90% of their living donors at required reporting periods

Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up

That proposal received overall favorable public comment, however, some regions, OPTN Committees, members of the general public, and the NKF Living Donor Council commented that requiring centers to report only donor status was insufficient and did nothing to help determine how organ donation could affect the future health of living donors.

Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up

During public comment, the ASTS opposed the proposal and requested that any new living donor follow-up policy be based on recommendations from the Joint Societies Work Group (JSWG).

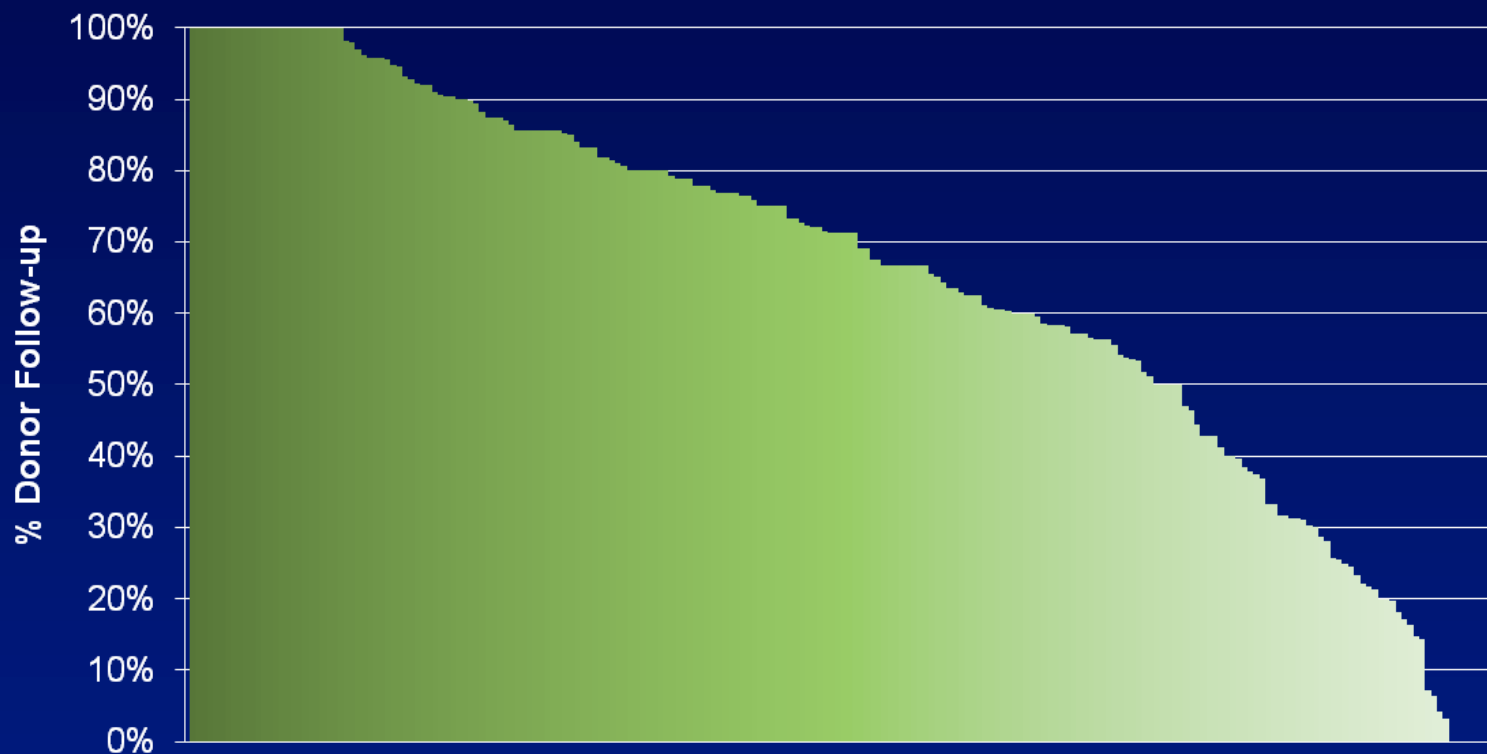
In response, the Committee determined that it would table the original follow-up proposal, and instead propose new follow-up requirements based on JSWG recommendations.

Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up

Affected/Proposed Policy and Bylaws: 12.8.3.1 (Reporting Requirements); UNOS Bylaws, Appendix B, Attachment I, Section XIII (Transplant Programs) D (2) Kidney Transplant Programs that Perform Living Donor Kidney Transplants

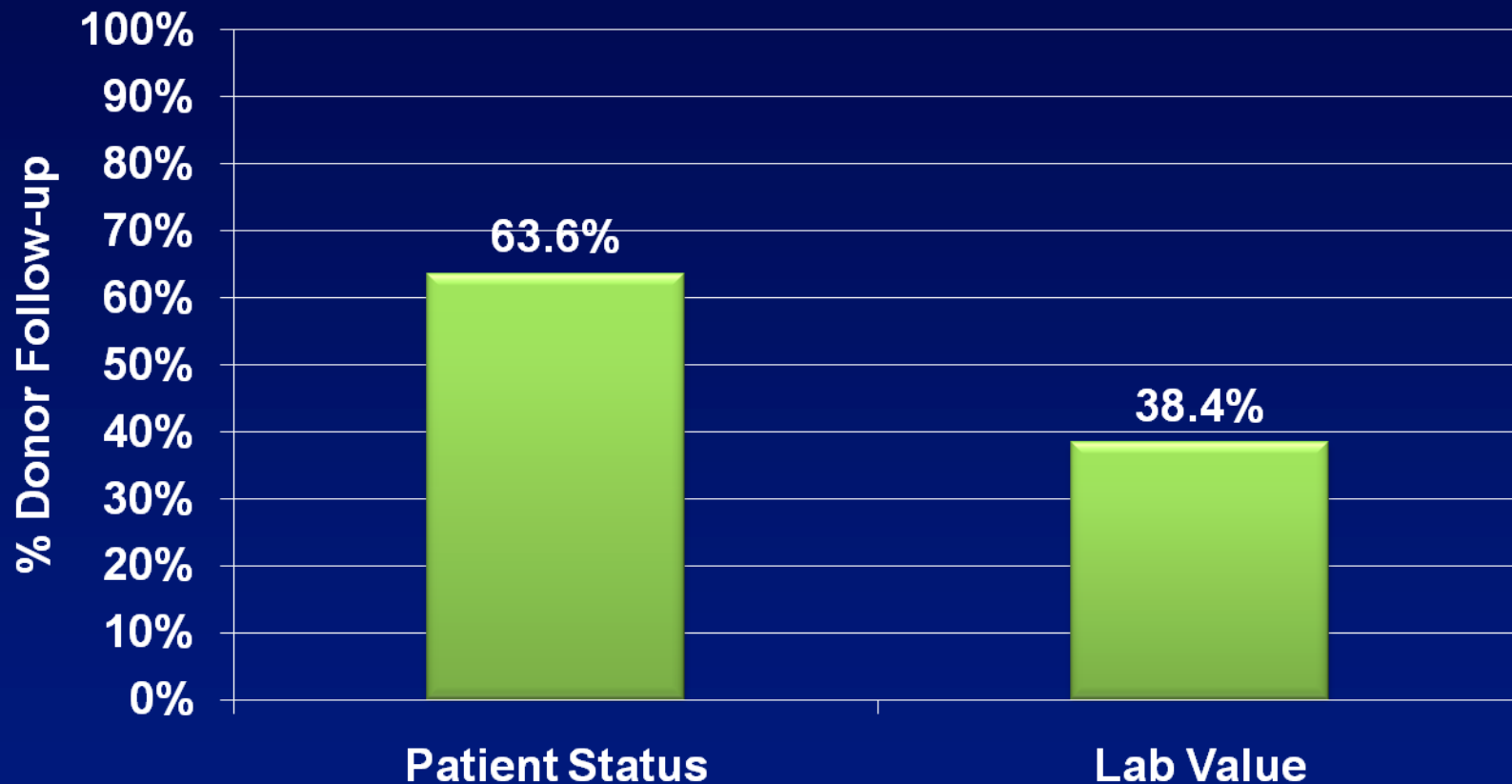
This proposal would eliminate the bylaw requirement for kidney transplant programs that perform living donor kidney recovery to develop and once developed follow written protocols for submission of required follow-up forms at 6 months, one-year and two-years post donation

Percent of Living Kidney Donors who have a Validated 1 Year LDF Form with a Known Patient Status (Alive or Dead, Not Lost-to-Follow-up) Dated within 2 Months of the Donation Anniversary by Center



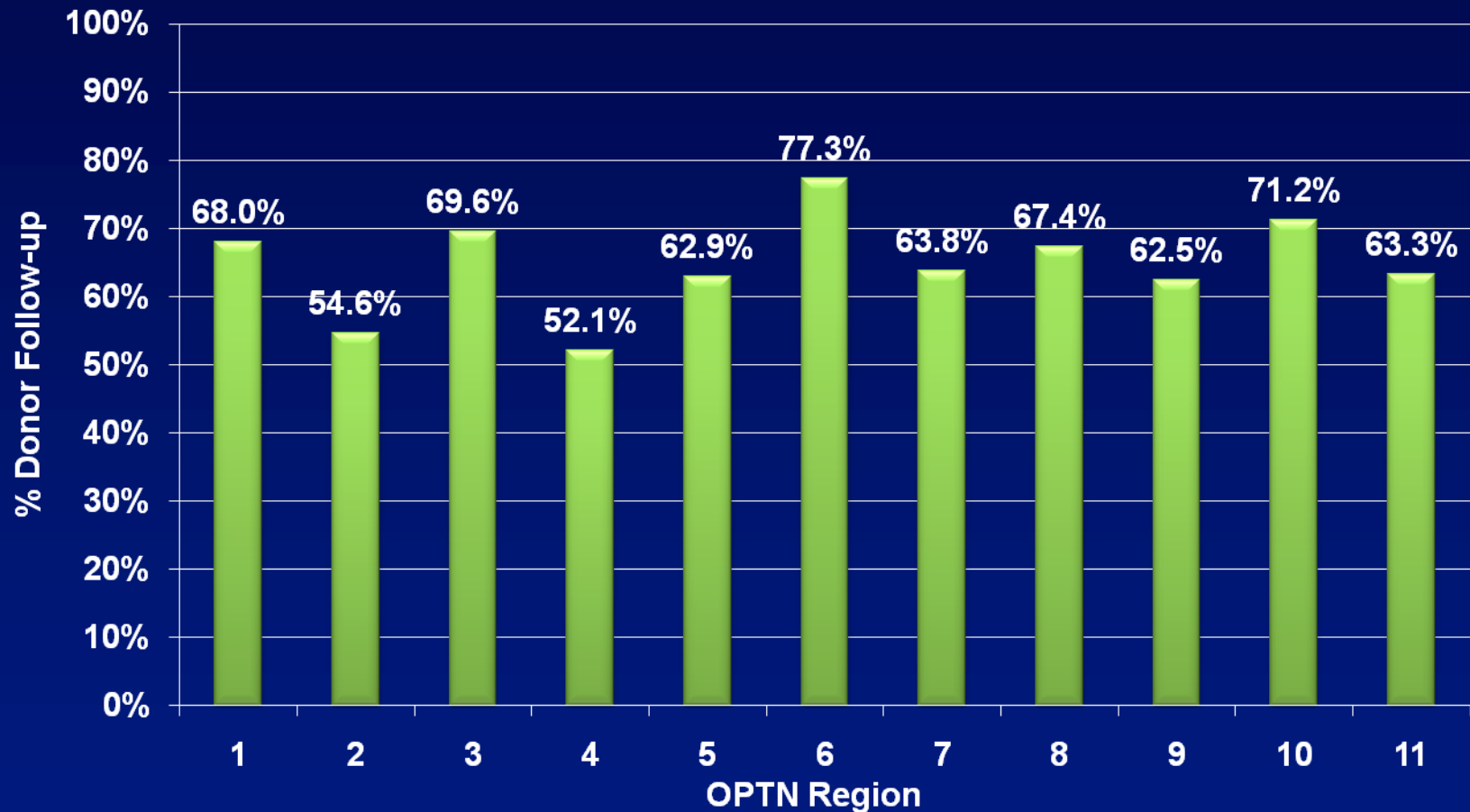
Note: Each bar represents 1 center. Includes living kidney donors who donated between 7/1/08 and 6/30/09. 26 centers reported status for 100% of their donors. 8 centers (blank area on right side of graph) reported status for 0% of their donors.

Percent of Living Kidney Donors who have a Validated 1 Year LDF Form with Lab Values OR a Known Patient Status (Alive or Dead, Not Lost-to-Follow-up) Dated within 2 Months of the Donation Anniversary
National Numbers (N=6070)



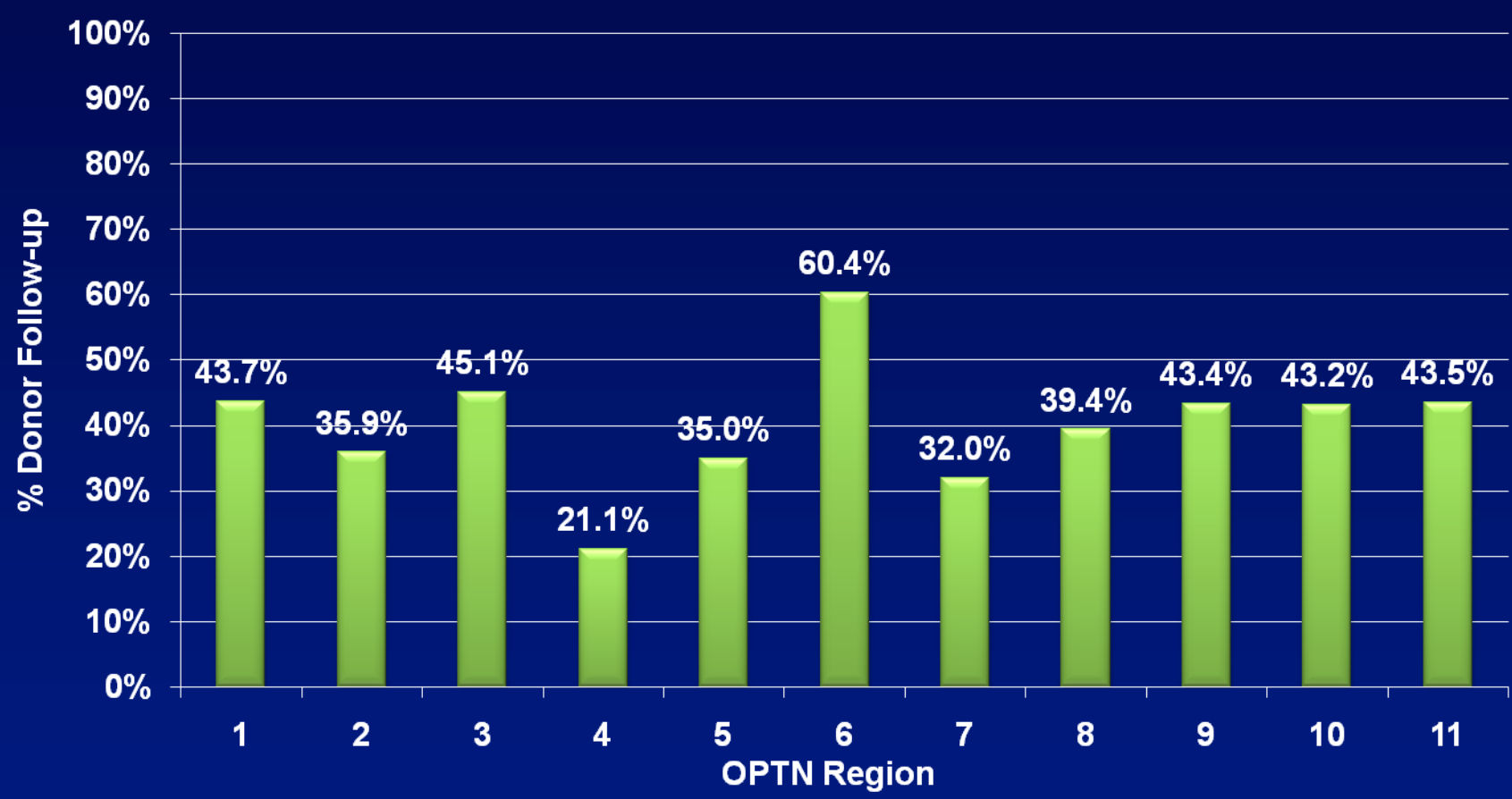
Includes living kidney donors who donated between 7/1/08 and 6/30/09.

Percent of Living Kidney Donors who have a Validated 1 Year LDF Form with a Known Patient Status Dated within 2 Months of the Donation Anniversary by OPTN Region



*Note: Each bar represents 1 OPTN region.
Includes living kidney donors who donated between 7/1/08 and 6/30/09.*

Percent of Living Kidney Donors who have a Serum Creatinine Value on a Validated 1 Year LDF Form with a Patient Status Dated within 2 Months of the Donation Anniversary by OPTN Region



*Note: Each bar represents 1 OPTN region.
Includes living kidney donors who donated between 7/1/08 and 6/30/09.*

Timeline for Kidney Donor Follow-up Proposal

- If this proposal receives favorable public comment, it could be considered by the OPTN/UNOS Board in **June 2012**, and if approved it would take effect in **September 2012**.
- The proposed new reporting requirement **would apply only to living kidney donors who donate beginning in September 2012**.
- Living donor recovery hospitals would first be required to report the new requirements for living donor follow-up **beginning in March 2013**

Timeline for Kidney Donor Follow-up Proposal

- The first cohort of donors to be reviewed will include donors who donate between **implementation (September 2012) and March 2013**.
- The six month LDFs for the last donor in this cohort will be due in **September 2013**.
- Centers must submit 100% of their forms within 6 months of their due date (Policy 7.81), so **no center could be out of policy compliance for not reporting required follow-up elements before March 2014**

Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up

12.8.3.1 Transplant centers that recover living donor organs must report accurate and timely follow-up data on the LDF form for at least 90% of their living kidney donors at the required reporting intervals, which at a minimum must include:

Donor Status

Patient status

Cause of death, if applicable and known

Working for income, and if not working, reason for not working

Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up

12.8.3.1 (cont)

Kidney Clinical Information

Serum creatinine

Urine protein

Maintenance dialysis

Donor developed hypertension requiring medication

Diabetes

Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up

12.8.3.1 (cont)

Complications

Has the donor been readmitted since last LDF form was submitted?

Kidney complications

Living donor follow-up data within 60 days of the six-month, one-year, and two-year anniversary of donation is considered timely.

Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up

The proposed changes to Policy 12.8.3 would replace the existing bylaw requirement for living donor kidney recovery hospitals to develop and comply with a written protocol for the submission of required follow-up forms at 6 months, one-year, and two-years post donation.

See pages 118-122 in the public comment document.

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